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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,563	04/02/2002	Namiko Yoshihara	159-72	4487

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EXAMINER
HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,563	YOSHIHARA ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 April 2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/2/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-6 are confusing because of the language "characterized in that" in independent claim 1, as the scope cannot be determined. It is suggested that conventional U.S. claim language such as "wherein" be used in amended claims. Further, it is unclear what "it" refers to; clarification is required.

B) Claims 7-14 are confusing because it cannot be determined what is encompassed by a "lower" alcohol in independent claim 7. Clarification is required.

C) Claim 11 is further confusing because "the biological component" lacks proper antecedent basis in claim 7. Correction is required.

2. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The further limitation of this claim relates only to "intended use" of the kit of claim 1 in the isolation of RNA – the kit as defined by its components is not further limited.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Lacroix et al. (US 5,795,722).

These claims are drawn to methods comprising: incubating a biological sample with a reducing agent, a coprecipitant, and a protein denaturant, in the absence of a protease; and directly performing alcohol precipitation.

Lacroix et al. disclose such a method in Example 1 bridging columns 12 and 13, wherein a blood sample is incubated with guanidine thiocyanate (protein denaturant), dithiothreitol (reducing agent), and glycogen (coprecipitant). After incubation, isopropanol precipitation is performed.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8-10, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacroix et al.

Claims 1-6 are drawn to kits comprising: a reducing agent, a coprecipitant, and a protein denaturant.

Claims 8-10, 12, and 14 are drawn to the methods as rejected above, with further limitations regarding incubation temperature (8 and 9), adding protein denaturant during alcohol precipitation (10), sample volume of 30-100 μl (12), and performance in a single 0.5 ml tube (14).

Lacroix et al. do not disclose the claimed kits, nor the further limitations of the claimed methods.

Regarding claims 1-6, one of ordinary skill in the art would have been motivated to make and use a kit comprising the required components because such a kit would have been clearly useful in carrying out the method of Lacroix et al. It was well known and common knowledge in the art at the time of the invention to package together reagents into a kit for the convenience of practicing methods requiring such reagents; indeed, Lacroix et al. disclose the desirability of kits in column 12, lines 31-46. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make and use the claimed kits.

Regarding claims 8-10, 12, and 14, one of ordinary skill in the art would have been motivated to modify the method of Lacroix et al. in the manner of the claims because such modifications would have clearly come under the heading of routine optimization, which does not contribute to patentability. Regarding claims 8 and 9, it was well known and common knowledge in the art that temperatures in the range of 55-65°C assist in denaturing proteins. Regarding claim 10, rinsing a pellet with alcohol mixed with guanidine and reprecipitating was also well known to add to purity. Regarding claim 12, although the serum sample of Lacroix et al. is 200 µl, it would have been readily apparent to the skilled artisan that sample volumes may be scaled up or down as desired, to include a volume in the claimed range. This applies to claim 14 as well; although the tube used in Lacroix et al. appears to be larger, 0.5 ml tubes were commonly used in the art and thus scaling down slightly to this size would have surely been obvious. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

5. No claims are free of the prior art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kenneth R. Horlick, Ph.D.
Kenneth R Horlick
Primary Examiner
Art Unit 1637

09/22/04